

The Following e-mails were received with regard to the September 6th, Pulmonary Allergy Drugs Advisory Committee Meeting on Spiriva.

They were available to the members prior to the meeting and the public at the meeting.

The FDA Review Division has received copies of the letters.

Kimberly Topper

Topper, Kimberly L

From:

Sent: Tuesday, August 27, 2002 5:22 PM

To: TOPPERK@cder.fda.gov

Subject: Spiriva

Dear Ms. Topperk:

As a user of Spiriva, I would like to add my voice to those who await FDA approval of this drug.

I have found that my exercise tolerance has increased markedly. While I have not, at this time, after 45 days using Spiriva, had a PFT to determine if statistical improvement is occurring, My ability to do more, and the increase in "quality of life" make me more than convinced that this drug will benefit a great many people.

I have severe emphysema and am on oxygen 24 hours a day but have been able to reduce my oxygen intake recently and still maintain my saturation stats. I can attribute this only to Spiriva. Please add my voice to the plea to approve Spiriva.

Thank you.

Sincerely,

Allen Warner

9/4/02

Topper, Kimberly L

From:
Sent: Tuesday, August 27, 2002 2:59 PM
To: topperk@cder.fda.gov
Subject: Spiriva

Dear Kimberly Topper,

Yes, I'm another member of Efforts vitally interested in having Spiriva (tiotropium), available in the US. Based on anecdotal case histories from members, it appears to contribute substantially toward better breathing and has already been tested, approved and made available in several countries.

Nearly 16 million Americans are estimated to suffer from Chronic Obstructive Pulmonary Disease, the fourth-ranking cause of death in the world -- but the only treatments available to us are those developed for asthma. As we are slowly dying from emphysema, chronic bronchitis and irreversable asthma (the 3 lung diseases grouped under the unwieldy umbrella name of "COPD"), the thought of ANY relief for our specific breathing problems is incredibly compelling.

Please add this letter to your stack, and -- Thank You!

Most sincerely,

Andi Emerson

Topper, Kimberly L

From: [REDACTED]
Sent: Saturday, August 24, 2002 10:46 AM
To: topperk@cder.fda.gov
Subject: FDA Spiriva Meeting

Dear Mrs. Topper and Committee members,
I am writing on behalf of myself and many other folks who are suffering with COPD. I am a member of a nationwide COPD support group - COPD-ALERT. whose members suffer the same as myself.
There are but few medications available for COPD patients, and those that we use are mostly for Asthma. Their effectiveness is limited.
I have had COPD for over 20 years and was positively diagnosed in early 1997.
Daily living can be difficult, there are many limits for me now. I am taking 3 different inhalers now several times a day, and at best, they keep me from being SOB for two to three hours.
I have read and spoken with people from other countries who are using Spiriva, and have heard nothing but positive things, regarding the drug. The biggest plus seems to be a much better quality of life.
If The Committee could feel confident in giving Spiriva the FDA approval, there are millions of us who would be eternally grateful.
Thank you for taking the time to read this.
Sincerely,
Ann C. Lutter

9/4/02

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Topper, Kimberly L

From:

Sent: Sunday, August 25, 2002 11:25 AM

To: topperk@cdcr.fda.gov

Subject: Spiriva

Kimberly Topper

Please have Spiriva approved as soon as possible.

Trial tests have shown that it will be beneficially to Emphysema patients. Any drug that will help us breath better and has been tested for a long period of time like Spiriva, should be available to us.

Thanking you,

Adolf Arens

9/4/02

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Topper, Kimberly L

From:

Sent: Monday, August 26, 2002 1:46 PM

To: topperk@cder.fda.gov

Subject: Spiriva Public Hearing Sep 6,2002

Hi Kimberly,

My name is Kathy Montero. I was dx with COPD in 1997.

I was hospitalized in 1996 with pneumonia and pleurisy. I thought the reason I was sob was because the pain was so bad in my left side.

Dr. told me I had scarred tissue on my lung, gave me meds for "asthma" and antibiotics and sent me home after 1 week.

That was in May. In Jan. of 97 my breathing was getting no better.

Went to Pulm. specialist and was given complete PFT.

I was 46 yrs. old, owned my own business, had plans to get married, and was just told I had COPD

I had smoked for 25 yrs. My Dr. told me that day, if I didn't stop right then, I would not see my 50th B'day. Scared the heck out of me. I quit and didn't look back ! Hey, I had been to some great 50th B'day parties and I wanted mine.

I exercise 6 days a week. trv to eat right.

So, enough about me. I am proud to be smoke free for 5yrs. 8 months.

I plan on being around to enjoy life best I can.

I truly feel SPIRIVA will help me to enjoy a better quality of life. Please approve SPIRIVA as soon as possible to give us COPD patients a chance for a better life and maybe a longer life. At this stage in my life, any improvement is wonderful.

Thank you for your attention on this matter.

Kathy Montero

Topper, Kimberly L

From:
Sent: Thursday, August 29, 2002 5:52 PM
To: topperk@cder.fda.gov
Subject: Spiriva

I am writting this note to encourage you to approve Spiriva for sale in the US. I am a member of EFFORTS{Emphysema Foundation for our right it survive]. We have been waiting a long time for this drug, which may help us to breath a little easier. There are many of our membership already getting the medicine from overseas, and our happy with the results they are getting, so please approve Spirivia for this country

Sincerly,
Gloria Goldberg

Topper, Kimberly L

From:
Sent: Friday, August 23, 2002 5:37 PM
To: topperk@cder.fda.gov
Subject: Spiriva

I believe it is time for COPD sufferers to have a medication approved
that will give them some relief.

Thank You, Barbara Jones

Topper, Kimberly L

From:**Sent:** Sunday, August 25, 2002 4:14 PM**To:** topperk@cder.fda.gov**Subject:** Spiriva Public Hearing Sep 6,2002

My name is Robert Brisendine and I am a COPD patient who is waiting, and praying for swift FDA approval of this drug. It is I know been well tested in clinical trials throughout the world and here in the USA. It is by all accounts the most significant and improved treatment for those of us who suffer from our diseases. I have followed this drug in everyway I could for the past several years now, since I first learned of it. In a disease area that has seen little valid, research into treatment options over many years now, this is one that holds promise of increaseing the quality of life for us and who knows may be the first step in developement of other treatments that may return some or even many of us to a limited level of productivity, I'd like that. Thats one of the worst things for me is even though my disability dosen't show like one with a wheelchair/missing limbs and so on, I am physically limited more so than those with obvisous physical limitations. This disease makes changing a light bulb in my house go from a 2 min task to a major job which depending on location I may not even be able to accomplish in any amount of time. I am anxiously awaiting FDA approval and US market availability with great expectation and high hope that it will work for me, yet I also realize that like everything it may not be for me, but at least I want the opportunity to find out and I want that opportunity as soon as possible, some people here have been fortunate enough to have benefited from Spiriva in the clinical trials and have had good results, they are fortunate in being in the right place and time and at least for them they know how much better they could perform with this new drug treatment, I have yet to hear any totally negative comments in regards to this drug.

PLEASE, PLEASE, PLEASE!!! Get on with approval of Spiriva so many of us here want the opportunity to try it, and best to believe even a small improvement is important because "when you can't BREATHE, NOTHING else matters"!

Thank you,

Robert Brisendine

Topper, Kimberly L

From:
Sent: Wednesday, August 28, 2002 7:30 AM:
To: topperk@cder.fda.gov
Subject: Spiriva Hearing

As a person afflicted with COPD I am extremely interested in the September 6 hearing. The possibility that Spiriva can arrest, or slow down, the progress of the illness is extremely heartening. I would hope that it could be made available to all COPD patients in the United States.

Carl Degen

Topper, Kimberly L

From:

Sent: Wednesday, August 28, 2002 6:24 PM

To: topperk@cder.fda.gov

Subject: Spirivia

To Whom it may concern:

I have allways investigated and done research on all the new drugs that I hope will be helpful to my husband who has a lung capacity of only 23%. I ran across Sprivia a few years ago and have been following all the testing and trials in various foreign countries.

When I saw that there would be a hearing with the FDA on this drug all I could think of was.....perhaps there will be a chance for my husband to see if this drug could perhaps give him a little bit of relief. Anything he does is an effort and all we who love him can think about is trying to find him some happiness while we can.

I urge you to take into consideration all the testing, trials and excellent results by those who have already tried it and get this drug approved here in America NOW!! Waiting another year may be too late for so many people.....they are counting on you to help bring some relief into their lives as soon as possible.....while we recognize it may not work as well for everyone it would be nice to be given the opportunity to try it NOW rather than later.

Thank you for any consideration of Sprivia and please consider it your number one priority before the end of the year!! For those with so little lung power left even a slight change is such an improvement.

Once again I urge you to give millions this chance for a better life before it is too late for so many.....

Thanks,
Carol Lowing

9/4/02

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Topper, Kimberly L

From:

Sent: Wednesday, August 28, 2002 11:35 AM

To: topperk@cder.fda.gov

Subject: SPIRIVA

Please seriously consider approving this drug. While I am newly diagnosed with COPD, supposedly severe, I am much better off at this stage than others. Who knows what I will need in the future. Everyday, on the support forums and mailing lists, I read of how others are suffering, unable to do anything for themselves, their breathing is so bad. The many people on oxygen, could be reduced, as has been seen in reports of patients in clinical trials, using this medication. They are able to work, as well as have a better quality of life. Almost everyday, I read of another person dying from complications of this disease, also those that are so depressed, they have no hope, they give up, or take their own lives. The pressure on their caregivers is also great, causing them to leave jobs and suffer depression as well, as they contemplate how to handle their loved ones. Have heard of many divorces, as a spouse is stretched to the limit taking care of a parent or child with this disease. The remaining spouse, can not cope with the person who is in this position and it is controlling their lives, so they leave the home. This can only put more people on the state lists for supporting their children. This is a vicious cycle. I have been reading the progression of those in the trials and for those who are buying this med out of the country, most are doing very well. While we all realize this can not cure the disease, it sure can help make it easier for those to live and function on their own. This change can only be possible if this medication is approved. Why cause people to buy it out of the country? Let it be available in the USA. While most people with this disease, have brought it on by smoking, there are those who have not, where it is genetic or job related. Let us remember the USA prospered greatly through out the states with the taxes on tobacco products, also sending them to our service men during the war. So many had a hand in this. Let us help people live a better life. Remember stress is also a toxin, many turn to alcohol, which in itself, causes many diseases and deaths.

Hope for a better future.

Sincerely,

Carole B. Buehler

Topper, Kimberly L

From:
Sent: Friday, August 23, 2002 3:33 PM
To: topperk@cder.fda.gov
Subject: Spiriva testimony

August 23, 2002

Ms. Kimberly Littleton Tupper
Center for Drug Evaluation & Research (HFD-21)
Food & Drug Administration
5600 Fishers Lane, RM. 1093
Rockville, MD 20857

RE: TESTIMONY IN SUPPORT of FDA APPROVAL
OF SPIRIVA

Dear Ms. Tupper and Members of the Committee:

I am writing this letter as an individual
and as a member of several national and
international COPD support groups: COPD-ALERT,
COPD_RT_TOO, Cheshire Medical Chronic Lung
Disease Forum, and COPD-Support Lung Forum. We
are among thousands of the millions in the
United
States who suffer from chronic lung diseases.

I have had asthma since I was a young child.
In
May 2000 (at age 42), I was also diagnosed with
COPD from no known cause. In December 2000, I
was diagnosed with emphysema also from no known
cause. These conditions combined to make it
very
difficult to perform everyday tasks and I was
becoming breathless at rest; I was
unsuccessfully
treated by three pulmonologists at home in

evaluation and treatment. My
pulmonologist has helped me develop an evolving
treatment plan that allows me to perform most
activities. Unfortunately, controlling my lung
conditions does require me to take medications
regularly which can cause side effects

including muscle twitching, increased liver enzymes, and osteoporosis. This is the same situation virtually all other folks with chronic lung diseases are faced with.

There are very few medications specifically for COPD. Most of the medications being used by those of us with COPD are asthma medications and are of limited effectiveness with often harmful side effects.

Like many others with chronic lung conditions, I have followed with great interest the development and clinical trials of Spiriva. It appears to be an improvement to ipatropium bromide (or Atrovent), which many of us have used successfully in the US and worldwide for many years, with an excellent safety record. All of the studies I've read on Spiriva appear very positive and I'm aware that it is available for purchase in several countries in Europe and elsewhere.

I look forward to having the prompt FDA approval of Spiriva, so it will be an important additional tool for our doctors to use with those of us with chronic lung conditions, especially COPD. Please do not hesitate to contact me if I can provide any further information. Thank you for this opportunity to state my position.

Very truly yours,

VALERIE CHANG

Topper, Kimberly L

From:
Sent: Sunday, August 25, 2002 11:31 PM
To: topperk@cder.fda.gov
Subject: FDA approval of Spiriva

Dear Ms. Topper- I am a lung pre-transplant candidate : . I have been listed only a short time, and it will be at least 2 years until transplant.

I own my own business at present, but may have to apply for Social Security Disability before long as , even with the present bronchodilators, I am declining.

I have read of the studies done in the US, and have heard that some folks with COPD, which is my diagnosis ,are helped by Spiriva, so much so that

they are having it imported, with the attendant Customs hassle. The cost is high and, though it doesnt improve pulmmonary function in everyone, there is enough positive evidence to make it available here ASAP.

If I were to work 2 years longer, I would pay approx. \$25,000 in federal income taxes per year as well as stay out of the public trough. I would

rather have the chance to work.

Spiriva is a close cousin of ipatropium, and seems to improve Pulmonary function in folks with COPD.

Please convey my request for approval.

Sincerely, Clayton E. Dart

Topper, Kimberly L

From:

Sent: Monday, August 26, 2002 11:41 PM

To: Topper, Kimberly L

Subject: SPIRIVA

To Whom it May Concern:

Regarding the meeting concerning approval of Spiriva for sale in the U.S.

So many, many people are suffering from COPD, and this medication offers a semblance of hope to them. I live in a very small town in and several people (including myself) are suffering from this disease. We were smokers long ago when it was considered safe; consequently, much of the damage was done then.

Please do not pass this off as a "they did it to themselves" item. After all there are thousands of people who are eating themselves into an early grave, and we certainly should not express that same attitude toward them.

Thank you in advance for your prompt attention to the matter of getting Spiriva on the market as soon as possible.

Doris Hirschy

Topper, Kimberly L

From:

Sent: Wednesday, August 28, 2002 5:24 PM

To: Topper, Kimberly L

Subject: Fda approval for Spiriva

I have been on Spiriva for 5 days now . In this short time I feel better. I was able to get it from the Netherlands. It is not fair that some of us can and others can't for various reasons. I would like everyone to reek the benefits of this drug.....I would like to see it approved earlier for all our benefits. I was afraid I would not live till next year to get it. Esther
Ripple member of EFFORTS

9/4/02

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Topper, Kimberly L

From:

Sent: Saturday, August 24, 2002 11:02 AM

To: Topper, Kimberly L

Subject: Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

Although not able to attend such a meeting, I would like to express my thoughts on Spiriva. I see it's been approved and proven successful in other countries in helping COPD patients live a more normal life style. Through various support groups on the internet I've spoken to people being treated with Spiriva and test subjects in the U.S. - all but one of those I've spoken with have given Spiriva high marks in improving their quality of life with this disease.

I am hopeful that Spiriva will be approved for use in the United States. Perhaps it's not the cureall that we are all looking for, but it appears to be a bit more beneficial than some of the treatments currently available to us with COPD.

Thank you

Richard Sharp

9/4/02

17

Topper, Kimberly L

From:

Sent: Saturday, August 24, 2002 10:15 PM

To: Topper, Kimberly L

Subject: Spiriva

Approve Spiriva, give my Mom a fighting chance. Most COPD patients have "nothing to lose". Give them some hope.

Sincerely,

Heller G. Hodge-Moore

Topper, Kimberly L

From:
Sent: Monday, August 26, 2002 10:01 PM
To: Topper, Kimberly L
Subject: Spiriva Public Hearing Sep 6,2002

My name is Jack Myers and I am a COPD patient who is waiting, and praying for swift FDA approval of this drug. It is I know been well tested in clinical trials throughout the world and here in the USA. It is by all accounts the most significant and improved treatment for those of us who suffer from our diseases. I have followed this drug in everyway I could for the past several years now, since I first learned of it. In a disease area that has seen little valid, research into treatment options over many years now, this is one that holds promise of increaseing the quality of life for us and who knows may be the first step in developement of other treatments that may return some or even many of us to a limited level of productivity, I'd like that. Thats one of the worst things for me is even though my disability dosen't show like one with a wheelchair/missing limbs and so on, I am physically limited more so than those with obvisous physical limitations. This disease makes changing a light bulb in my house go from a 2 min task to a major job which depending on location I may not even be able to accomplish in any amount of time. I am anxiously awaiting FDA approval and US market availability with great expectation and high hope that it will work for me, yet I also realize that like everything it may not be for me, but at least I want the opportunity to find out and I want that opportunity as soon as possible, some people here have been fortunate enough to have benefited from Spiriva in the clinical trials and have had good results, they are fortunate in being in the right place and time and at least for them they know how much better they could perform with this new drug treatment, I have yet to hear any totally negative comments in regards to this drug.

PLEASE, PLEASE, PLEASE!!! Get on with approval of Spiriva so many of us here want the opportunity to try it, and best to believe even a small improvement is important because "when you can't BREATHE, NOTHING else matters"!

Thank you,

Jack R Myers

Topper, Kimberly L

From:

Sent: Tuesday, August 27, 2002 8:28 PM

To: Topper, Kimberly L

Subject: Spiriva

Dear Ms. Topper:

I am writing you in regards to the meeting concerning approval for Spiriva. I have COPD and am a member of EFFORTS(Emphysema Fighting For Our Right To Survive) . The information I have heard about the new drug is amazing. My pulm. doctor says it will be wonderful. There is very, very few effective drugs for Emphysema and I hope that it will soon get approval for use in the US.

Thank you so much.

Carrie M. Shelor

Topper, Kimberly L

From:

Sent: Saturday, August 24, 2002 12:05 PM

To: Topper, Kimberly L

Subject: FDA Approval Tiotropium

To Committee, I am an emphysema Patient and am involved in a 6 month test at ' on Spiriva (Tiotropium) I am not sure at this point if I am on the real thing or a placebo. I am almost 2 month's into the Test and hopefully it will be approved so that at the end of my test I will be able to continue taking this medication without having to purchase overseas. I also belong to an online support group called Efforts (Emphysema Foundation for our right to Survive). Some of our members are obtaining this medication from Holland and most are quite happy with the results. Our website is www.emphysema.net There fare a number of testimonials of our members regarding this medication. Thanks Much
Jim Culpepper

Topper, Kimberly L

From:
Sent: Monday, August 26, 2002 1:31 PM
To: Topper, Kimberly L
Subject: spiriva

Dear Kimberly,

I will not be able to attend the meeting on Spiriva, but I wish to encourage the panel to consider release of spiriva as soon as possible. I have been in contact with several people who have been able to obtain the drug from the Netherlands and most are showing remarkable improvement.

I am a 57 year old who suffers from severe COPD and would love to be able to use spiriva. I have considered participation in one of the clinical studies currently being conducted in the United States. I made the decision not to participate because of the 2 hour commute to the facilities conducting the studies. I am also fairly stable on my currently prescribed drugs and don't want to give them up to be part of a blind study where I could end up being administered a placebo.

Please consider allowing spiriva to become a legally prescribed drug here in the United States. Anything that will increase the quality of life, with so few side effects, deserves to be part of a legally acceptable treatment program for COPD.

Thank you for your time and attention,
Mary Beth Nelson

Topper, Kimberly L

From:
Sent: Monday, August 26, 2002 10:17 AM
To: Topper, Kimberly L
Subject: Spiriva

Dear Sirs:

I have been taking Spiriva for two months and my breathing has improved significantly. I have emphysema and Spiriva has greatly improved my quality of life. I urge you to approve this drug so that those that suffer from disease can benefit.

Sincerely,

Joseph Rabushka

Topper, Kimberly L

From:
Sent: Monday, August 26, 2002 10:34 PM
To: Topper, Kimberly L
Subject: Let's Get Spiriva to USA asap please!

Hello. I have emphysema and am very anxious for Spiriva to be legal in the USA. This med has helped some people, weven with emphysema. I am only 57 years old and have to use oxygen sometimes. I have not smoked in over 20 years. I would like a reasonable life for whatever I have left. Please cut through the red tape and get this medication here to help us.
Respectfully,
Joy Molloy

Topper, Kimberly L

From:
Sent: Tuesday, August 27, 2002 1:24 PM
To: Topper, Kimberly L
Subject: RE:Spiriva

I have very severe Emphysema, with a lung capacity of 19%. I pray that Spiriva becomes available soon. It takes new medications so long to be approved--this might be the last new one that will ever be available for me to try to improve my breathing and my quality of life. Thanking you in advance.

Karen D. Hodge

EFFORTS Member
(Emphysema Foundation For Our Right To Survive)

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Topper, Kimberly L

From:

Sent: Saturday, August 24, 2002 1:44 PM

To: Topper, Kimberly L

Subject: spiriva

From Carolyn Poe: I have heard good things about tiotropium for COPD patients. I hope it will be approved as I understand there may be fewer side effects than the present inhalants have. The side effects from Atrovent are bothersome. I will be on a medication for COPD for the rest of my life. Thank you.

9/4/02

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Topper, Kimberly L

From:
Sent: Monday, August 26, 2002 10:30 AM
To: Topper, Kimberly L
Subject: RE: Spiriva

I am a 54 year old female with asthma and COPD. I learned about Spiriva from my internet support group EFFORTS. Those that are fortunate enough to be able to get the drug from Meeburg pharmacy have reported exceptional improvement from Spiriva.

If this drug could get FDA approval in the USA, I think it would give those of us with this horrible disease something that would be most beneficial and give us some encouragement.

Not everyone can order the Spiriva from Meeerburg, which is a shame. I sincerely hope that this drug will be available in the USA within the near future.

Laura Mangum Rigdon

Topper, Kimberly L

From:

Sent: Friday, August 23, 2002 12:44 PM

To: Topper, Kimberly L

Subject: Spiriva Hearing--SUPPORTING

Dear Ms. Kimberly Littleton Topper,

I am VERY interested in seeing Spiriva approved for use in the US, as it has been used successfully in other countries and the results of the clinical trials show such great promise for those of us with chronic lung diseases. It appears closely related to Atrovent (also known as ipatropium bromide), which many of us have used successfully for m-a-n-y years. I will not be able to attend the hearing due to great distances and expenses involved, but am greatly interested in the proceedings.

Valerie Chang

9/4/02

28

Topper, Kimberly L

From:
Sent: Sunday, August 25, 2002 6:09 PM
To: Topper, Kimberly L
Subject: Spiriva

Dear Kimberly Topper:

I am a woman of 68, who was diagnosed in my mid thirties, so have been taking inhalers and puffers and various medications for over 20 years. Quite smoking shortly after diagnosis, and have been hospitalized about 20 times. At present if I took all the puffs I was prescribed to take, it would be 32 times a day. I am in reasonably good health, have taken care of myself, exercise, am on O2 at night and for exercise. I also have a mother in law 95 and mother 94 I do for. Life would be so much simpler and easy if I had less medications to remember and the time to take them. And it does take a lot of time to get them all down 4 times a day, with Spiriva, it would be a couple puffs in the morning, and I could get going. It doesn't make any sense to take so many, when one would do the job. Please I beg of you, get this out on the market and make life better and easier. We have a tough time of it, life can be better if we get at least the right to try something.

Thank you,
Do all you can and then a little more
LOIS, :

Topper, Kimberly L

From:
Sent: Sunday, August 25, 2002 7:19 PM
To: Topper, Kimberly L
Subject: Approval of Spiriva

I won't bore you with the name and web site of the Emphysema group I belong to as I'm sure you've seen enough of it.

However, as a member of the large group of those who suffer from an advanced case of Emphysema, I am eager for the approval of Spiriva to proceed at Warp speed. Please do all you can to help us who are in such desperate need for a drug developed for Emphysema sufferers and, from all accounts, quite successful. Currently our only help is from Asthma drugs, not exactly what we need.

--

Sincerely, Maggi MacPhee

Topper, Kimberly L

From:
Sent: Sunday, August 25, 2002 4:28 PM
To: Topper, Kimberly L
Subject: Approval of Spiriva

As a victim of Emphysema and in serious disability, I urge a quick approval of Spiriva. Those of us who need all the help we can get, wish that it be approved sooner, not later.

Thank you for your efforts.

--

Marg Sampson-'

Topper, Kimberly L

From:

Sent: Monday, August 26, 2002 10:47 AM

To: Topper, Kimberly L

Subject: Spiriva

Hello...

I'm a 60 year old woman with severe COPD. I have been struggling to breathe for years. I'm on oxygen 2 liters for sleep and walking, 3 liters when exercising.

I have been taking Spiriva for four weeks now and saw an improvement almost from the start. I'm able to do more in my daily life with less of a problem becoming short of breath. I'm also able to do things without constantly having to be aware of how I'm breathing.

I first learned of Spiriva on my on-line support group EFFORTS. I learned how to order this medication from EFFORTS \

We number approximately 1,000 people, all suffering from some form of this disease. There are so many of them waiting for FDA approval so they can get some relief. Please do all you can to make our lives a bit easier. Thank you.

Marie McGrath

Topper, Kimberly L

From:
Sent: Wednesday, August 14, 2002 8:14 PM
To: Topper, Kimberly L
Subject: spiriva

My name is Marilyn Nicotra and I have emphazema. Please approve the drug spiriva at the meeting. I believe it will help many people who have to struggle every day just to breath.
... We who have lung disease are all depending on the new drug to give us hope and life. Thank you for you time. Marilyn Nicotra

Topper, Kimberly L

From:
Sent: Friday, August 23, 2002 6:55 PM
To: Topper, Kimberly L
Subject: Spiriva

I am a COPD (emphysema) patient. It has been 15 years since my diagnosis and I likely had the disease another two or three years before that. I am now on oxygen 24/7 and cannot stand or walk for any length of time without complete breathlessness. My wife must help me take my once-a-week shower, help me brush my teeth and, at times, help me go to the bathroom. Out of financial necessity, I still work, using an oxygen concentrator and electric scooter to do so, but with great difficulty. As you may know, the available medications were all developed for asthma and are of very limited efficacy in treating emphysema. Now, there's Spiriva. Reading the literature, I see a glimmer of light at the end of a very dark tunnel. I need this medicine. I would appreciate anything you can do to speed up the process.

Michael Wright

Topper, Kimberly L

From: [REDACTED]
Sent: Saturday, August 31, 2002 5:04 PM
To: Topper, Kimberly L
Subject: Spiriva

My name is Mike Parker. I have been using Spiriva for about 45 days now. I got your email address through an internet community I belong to by the name of EFFORTS. If you think it will help, I will be glad to attend your meeting on 9/6/02 in Gaithersburg, MD.

Mike Parker

Topper, Kimberly L

From:**Sent:** Friday, August 23, 2002 11:19 PM**To:** Topper, Kimberly L**Subject:** Spiriva

Please if there is any chanch of getting this in the United States to just one person with this terrible thing known as copd, then let us have it. It would be so nice to get up of morning and take a shower or read the paper, and enjoy the morning. But by the time I get up at 8 or 8:30 and do all my treatments and and take all my meds. It's about 10 and sometimes it is so painful and so hard to breathe that you are so worn out you don't know if you can go on. So if there is something out there that can helps us please let ue be able to get it, and do something that others take for granted. BREATHE I know it's my fault that I'm this way, because back when I was young smoking was the thing to do, everyone did it. All the stars and all the cool billborads they put up and the TV and radio talked about how great that it was. And even on the show MY THREE SONS the father came home from the office and lit up his pipe. And I'm a woman with 5 grandkids and would love to stay around and watch them for awhile longer, and I'm only 53 now. Well thank you for your time and I hope that you can really go in there and fight for us, because we don't have the breathe to fight for our selfs. Billie Webb

9/4/02

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Topper, Kimberly L

From:

Sent: Sunday, August 25, 2002 7:36 PM

To: Topper, Kimberly L

Subject: FDA Meeting

Hello,

I am a 70 year old Emphysema patient and have been taking Spiriva for the past 2 months through my Pulmonologist.

I have had not adverse effects whatsoever, only help. Instead of using three inhalers 4 times a day, I now only use Foradil twice daily and Spiriva once daily.

I cannot tell you the difference it has made in my life. It is such a pleasure to be able to make my bed without stopping to breathe, or take a bath and enjoy it without having to huff and puff. It is my honest hope that the FDA will hurry with the approval of this medication as I know there are hundreds of people out there praying and waiting for some thing to help them enjoy their lives as best they can.

Thank you for your time

Joan Breeden

Topper, Kimberly L

From:

Sent: Monday, August 26, 2002 12:25 PM

To: Topper, Kimberly L

Subject: Spirivia Approval for US

Hello Kimberly:

My name is Tony Hamel and I have emphysema.

This drug is the ONLY drug currently that has been formulated for emphysema.

All the other inhalers, Combivent, Serevent, Atrovent, Flovent are medications that are used for emphysema but were formulated for asthma and chronic bronchitis treatment.

Please see that Spirivia is approved for sale in the US.

I belong to 4 COPD support online groups and we have a number of members who have been in the Spiriva trials and the reports are glowing.

This is very important to the quality of life for emphysema sufferers.

When you can't breathe, nothing else matters.

Spirivia helps this condition more than any other medication on the market today and Spirivia is a once a day dose whereas the other inhalers are twice a day up to 4 to 6 times a day and do not have the same positive results as Spirivia.

WE as emphysema sufferers need this medication.

There are more than 16 million of us.

I have had a lung transplant and still have to use combivent 4 times a day because my native lung still has emphysema and functions very poorly.

With the Spirivia, I would have to use it once a day and get better results.

Thank you for your consideration and time.

Tony Hamel

Topper, Kimberly L

From:
Sent: Wednesday, August 28, 2002 2:37 AM
To: Topper, Kimberly L
Subject: SPIRIVA

Dear Committee Members;

I am writing this note to ask you to please approve the new inhalant, SPIRIVA, for public use.

I am a victim of emphysema, also classified as the 'umbrella' term, COPD. I have been on oxygen at 2L. twenty-four hours a day, seven days a week. I was horrified to discover there are very few medications that are designed to treat emphysema. Most of the medications we use were designed to treat asthma, and the two diseases are not alike. We have ADVAIR now, which was a god-send. Now I no longer need to take 3 puffs of one inhaler and 2 puffs of another twice a day. By using ADVAIR, at 1 puff twice a day, I can eliminate 10 puffs of two different inhalers. I believe less is often better than more, and it certainly proved to be true in this case.

Now we have the opportunity to experience a new medication that promises to be better yet. I am not an uneducated woman and have learned much since

contracting this disease. I do not believe this medication will be the cure-all so many are hoping for, nor do I believe it will benefit everyone who tries it. But for goodness sake, what else do we have to offer us hope?

I do believe there are people who will benefit greatly from this new medication. Several members of my Internet Support Group called EFFORTS have already gotten their doctors to write prescriptions for SPIRIVA, which were honored by pharmacies in other countries where SPIRIVA is available. Most of these people have been reporting on a regular basis about their progress, if any. And I am happy to say, most of them are improving.

PLEASE, APPROVE SPIRIVA FOR SALE IN THIS COUNTRY AS SOON AS POSSIBLE.

When you can't breathe....when you are suffocating slowly to death....every day matters. Give those of us with no hope, some hope.

Thank you,
Sincerely,
Mrs. Peg DeAngelo

Topper, Kimberly L

From:

Sent: Monday, August 26, 2002 9:34 PM

To: Topper, Kimberly L

Subject: FDA Hearing /Spiriva/ Sept 6th

Kimberly,

I belong to an internet support group for COPD patients called EFFORTS. We have been looking forward to SPIRIVA for a long time. Many of our members have already started on it by ordering from a pharmacy in Holland. I am planning on asking my doc to write me a prescription.

We know that it is not a cure but it seems to be making life much more enjoyable for a lot of people. It needs to be available here in the US so the docs will feel better about prescribing it for us. We need drugs that are developed for our disease and now that one is available it is giving us real hope.

Hope it is made available here soon.

Rosemary Abshire

9/5/02

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Topper, Kimberly L

From:

Sent: Tuesday, August 27, 2002 8:50 PM

To: Topper, Kimberly L

Subject: Spiriva

I am an Emphysema sufferer and have heard a lot about the new drug Spiriva. I have been waiting to try it for about a year now. Please, do what needs to be done to get it approved as quickly as possible.

Thank You

Ruby Lyskowinski

Topper, Kimberly L

From:

Sent: Thursday, August 29, 2002 1:58 PM

To: Topper, Kimberly L

Subject: Spiriva FDA Committee Meeting on September 6th

Dear Ms. Topper:

It is my understanding that you are the appropriate person for me to send my letter of support regarding the approval of Spiriva in the United States.

I am only one of millions of individuals suffering from COPD/Emphysema. I am currently on both long term and short term inhalers for my illness. I have followed the research on Spiriva with great interest and have also read several reports from those who have been in Spiriva research trials. All that I have read sounds very encouraging and appears to offer hope for improvement in quality of life for many suffering from COPD. While not a "cure" this medication does appear to result in improvement for many people. For those suffering with this disease, even a little improvement makes a big difference!

Please advise those who will be considering the approval of this drug to please do so as quickly and efficiently as possible.

Thank you for your help in this matter.

Roberta M. Parker

Topper, Kimberly L

From:

Sent: Wednesday, August 28, 2002 9:59 AM

To: Topper, Kimberly L

Subject: Spiriva

Ms. Topper,

I have COPD and am eagerly awaiting the approval of Spiriva by the FDA. Many of us with this disease have or are considering ordering it from the Netherlands. We should be able to get this medicine in our own country. It has been proven to be effective and many of us don't have enough time left to wait for long approvals by the FDA. Please encourage the committee to approve Spiriva.

Thank You,

Rosie Winters

Topper, Kimberly L

From:

Sent: Thursday, August 29, 2002 9:13 AM

To: Topper, Kimberly L

Subject: Re:

MsTopper.

Thank you for responding.

I am a COPD patient and am interested in the FDA meeting taking testimony on Spiriva. There are very few medications available for those of us with COPD. We presently have adopted Asthma medications because that is all there is. They are for the most part ineffective. I belong to 2 Internet groups and I have been reading a great deal of information on this new drug-Spiriva. The testimonies of those using it in trials and the international reports are very promising. COPD patients in the U.S. are anxiously awaiting release of this new drug. It is a terrible experience when you cannot breathe. I pray that this drug will be released in the near future so that the thousands of COPD patients like myself will have the chance to have some relief. in this terrible breath taking disease. Thank you for reading this.

Sincerely,

Sharon Young

Topper, Kimberly L

From:

Sent: Saturday, August 24, 2002 11:51 AM

To: Topper, Kimberly L

Subject: Re: Spiriva

My name is Jean Moessner. I am 65 years old and have severe emphysema/COPD. I am on supplemental oxygen 24/7. I am asking you to please allow the sale of Spiriva in the United States. I am sure you have studied all the reports from the Netherlands with regard to their trials and read all the accounts of the people who have participated. The medicine does help people with emphysema/COPD. Some people have had great success others moderate success, but even a little improvement in my breathing is better than what I am living with now.

Im sure you are aware that all the medications currently available to people with emphysema/COPD was tested and manufactured for people with asthma. Some of these medicines do help in a limited way. For them to be effective I have to use several inhalers in addition to a nebulizer several times a day.

Please consider allowing Spiriva to be sold in the US. Thank you for your attention.

Jean Moessner

Topper, Kimberly L

From:

Sent: Saturday, August 24, 2002 11:39 AM

To: Topper, Kimberly L

Cc:

Subject: NDA 21-395 Spiriva

Dear Ms. Topper:

I was diagnosed with copd almost 4 and a half years ago. I have since quit smoking and am still able to work full time. Since some of the members of Efforts who have taken Spiriva have said that it decreases their shortness of breath and they are able to do more, I would like the FDA to approve this drug so that I can benefit from it and continue to keep teaching for a long time. I believe approving this drug for immediate prescription dispensation, will reduce the number of exacerbations and hospitalizations experienced by copders.

Thank you.

Sincerely,

Kathleen Lukas

Topper, Kimberly L

From:

Sent: Saturday, August 31, 2002 6:06 AM

To: Topper, Kimberly L

Subject: Spiriva

Ms. Topper,

If you only knew the thousands of people that are desperately waiting for something to help the horrible effects COPD has on our body, surely the new drug Spiriva will be accepted into the US very soon. I have severe COPD, have lost one sister to this disease and continue to pray for more research on this before it is too late for a lot of us. We know Spiriva is not a cure but to have an improved quality of life sounds like heaven to me.

Thanks

Vera Franks

Topper, Kimberly L

From:

Sent: Saturday, August 24, 2002 10:04 AM

To: Topper, Kimberly L

Subject: SPIRIVA

My name is Jeanette Vielhaber

have been diagnosed with COPD for 8 1/2 years.

I have been on different meds over the years and they have all been designed for asthma, not emphysema but that is all that is available for us. Because of having to be on Prednisone at different times and because of the steroids in my inhalers I have lost the fatty tissue in my arms and legs. I have frequent skin tears and bruising. I am on 02 2L at rest and 3L for exercise. I am unable to function without a great deal of support from my husband who does all the cooking, cleaning, shopping, etc. Whatever I used to do, he does now. He is 72 years old and I am 71.

I am writing to you as an individual whose life has been seriously affected by not having proper medication for many years. Being a member of COPD-ALERT, I share their need for medication that is for Emphysema.

Jeanette Vielhaber

Topper, Kimberly L

From:
Sent: Monday, August 26, 2002 7:10 PM
To: Topper, Kimberly L
Subject: Spiriva approval

Please allow Spiriva to be sold in this country.
It's the best drug to come along in years - especially
for us COPD patients. We need this drug desperately!

Thank you. Vincent Neill

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Topper, Kimberly L

From:
Sent: Monday, August 26, 2002 12:02 PM
To: Topper, Kimberly L
Subject: FDA Spiriva Hearing

Kimberly L. Topper
Aug.
26, 2002
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane, RM. 1093
Rockville, MD 20857

Dear Ms. Tooper,

I am writing to you to let you know that I suffer from emphysema and use supplemental liquid Helios O2, 24/7. I am 68 years old, had whooping cough as a 3-month old baby which damaged my lungs enough that after smoking many years, I developed emphysema, probably 15-20 years ago. None of these pitfalls were known in the 1940s, but they are known now. In fact, when I was in high school, in the '40s, the doctors advertised smoking on the billboards, etc., as a "sophisticated, glamorous thing to do."

In 1997, I was so "short of breath" that I had to quit smoking or quit breathing. I quit smoking, cold turkey, and the emphysema stabilized for a while, but then I have started to go downhill rapidly. Thus, the O2 was started June '02, just two months ago.

The only meds. now available to emphysema patients are essentially those for asthma patients, most are ineffective and some have harmful side effects for me.

I am looking forward to Spiriva being approved for use in the US, so that I may use this new med. I am writing to you, both as an individual with emphysema and as a member of COPD-ALERT, the internet support group, made up of many, many people like myself.

Thank you.

Virginia Dare Mattiza

Topper, Kimberly L

From:

Sent: Monday, August 26, 2002 5:00 PM

To: Topper, Kimberly L

Subject: Spiriva

Please ok it for the united States as I hear it has helped a lot of people and we do need help to keep going.
Thank you. Virginia Donnelly

9/4/02

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Topper, Kimberly L

From:

Sent: Monday, August 26, 2002 12:25 PM

To: Topper, Kimberly L

Subject: Spiriva Public Hearings

August 26, 2002

My name is Zita Madison. I am 46 years old and suffer from severe COPD. I am one of many waiting and praying for a swift FDA approval of Spiriva. It has tested well in clinical trials both here and abroad. Many of our friends and neighbors overseas already have seen and or reaped the benefits of this drug. Many in the USA, with the help of their physicians have been successful in imported this medication. While I understand not all have seen positive results many have. I for one would like the opportunity to have this medication available to me.

It is by all accounts the most significant and improved treatment for those of us who suffer from our diseases. I have followed this drug in everyway I could for the past several years now, since I first learned of it. In a disease area that has seen little valid, research into treatment options over many years now, this is one that holds promise of increasing the quality of life for us and who knows may be the first step in development of other treatments that may return some or even many of us to a limited level of productivity, I'd like that.

I have three children. Two are married and I am still attempting to raise an 11 year old son. I say attempting, as, many days I cannot even dress myself. My family has seen me go for a very active Special Education teacher to a handicapped women that must rely on many for simple everyday things.

COPD is a horrible, horrible disease. While it is the fourth largest killer of people in the USA, those of us suffering have seen little strides in research. For some of us Spiriva may be the answer we have been waiting for. It just may return us to more productive citizens. It just may allow me to return to the classroom and the children I love. At 46 I am not proud to be receiving Social Security Disability. I take over 28 medications a day. Think about that. Maybe with the help of Spiriva I could drastically lessen that amount.

I pray for a swift approval of Spiriva. It just may be the drug that will allow me to attend my youngest sons high school graduation.

Thanking you in advance for your time and consideration.

Sincerely,
Zita D. Madison

9/4/02

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